

REMARKS

I. STATUS OF CLAIMS

Claims 1-37 are pending in this application. Claims 1-12 were withdrawn from consideration by the Examiner as being directed to non-elected subject matter. The phrase "optionally with a pharmaceutically acceptable carrier" has been deleted from claims 13, 18-21, 26-27, 29, 30, 33, 34, and 36. Claims 13, 18, 26, 27, 29, and 33 are further amended to include provisos. Support for the amendment to claim 13 can be found on page 89, line 9 to page 90, line 7 (Scheme 13) in the substitute specification. Claim 21 has been amended to delete the compound of formula 1 (AC). In the interest of clarity, the word "is" has been changed to "has" in claims 31 and 32. No new matter has been added by the amendments provided herein.

II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejects claims 13-21 and 25-37 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at pages 4-5.

While Applicants do not agree with the Examiner's assertions, in order to advance prosecution and without disclaiming any subject matter, Applicants have deleted the phrase "optionally with a pharmaceutically acceptable carrier" from independent claims 13, 18-21, 26, 27, 29, 30, 33, 34, and 36. In view of these amendments, Applicants submit that claims 13-21 and 25-37 are clear and definite. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. REJECTIONS UNDER 35 U.S.C. § 102

A. Rejection based on Ewing et al. (Carbohydrate Research, 1999, Vol. 321, pp. 190-196)

The Examiner rejects claims 13-14 and 25 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ewing et al. (Carbohydrate Research, 1999, Vol. 321, pp. 190-196) ("Ewing"). Office Action at page 6. The Examiner asserts that compound 10 in Ewing "anticipates compounds of formula (I) when CR'₂ come together with R¹ or R³ to form a substituted 5-membered ring, the other R¹ or R³ that did not come together with CR'₂ to form a substituted 5-membered ring is H, R⁴ and R⁵ is H, and R⁴ and R⁵ is OH." Office Action at pages 6-7. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

"For anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. § 706.02(V). The identical invention must be described in as complete detail as is contained in, and must be arranged as required by, the claim. See M.P.E.P. § 2131. Indeed, in order to anticipate the claimed invention, a reference must "clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing and combining various disclosures." *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972).

Applicants submit that compound 10 is not within the scope of formula (I) as claimed in claims 13-14 and 25. In compound 10, the 5-membered ring is substituted with a -CONH₂ group. In formula (I) in claim 13, the 5-membered ring does not have a -CONH₂ substitution at this position. Applicants' claim 13 reads in part, "if R² is CR'₂,

then R^1 or R^3 can come together with CR'_2 to form a substituted or unsubstituted 5-7 membered ring that can include one or more heteroatoms." Claim 13 further reads that each R' (R prime, not R^1) is "independently hydrogen, lower alkyl, alkylene, alkenyl, aryl, or aralkyl of C_1 - C_6 ." Thus, R' in claim 13 is not a $-CONH_2$ group. As Ewing clearly does not teach every element of the claimed invention, Ewing does not and cannot anticipate claims 13-14 and 25. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

B. Rejection based on JP 5-140179 A to Yoneda et al.

The Examiner rejects claims 19 and 33 under 35 U.S.C. § 102(b) as allegedly being anticipated by JP 5-140179 A to Yoneda et al. ("Yoneda"). Office Action at page 7. The Examiner asserts that "[t]he compounds of Yoneda is the compound in instant claims 19 and 33 when R^4 and R^5 are H, R^4 ' and R^5 ' are OH, W is O, Z' is N, and Z is CX, where X is H." *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. § 2131 (emphasis added). Here, Yoneda fails to teach or suggest each and every element of claim 19. Specifically, Applicants point out that in claim 19, Z' is either CH or CX, but Z' can not be a nitrogen atom, as the Examiner asserts. Accordingly, Yoneda does not and cannot anticipate claim 19 of the present application.

While Applicants do not agree with the merits of the Examiner's assertions regarding claim 33, in order to advance prosecution and without disclaiming any subject matter, claim 33 has been amended to include the proviso that "when Z is CH, R^b is

hydrogen, R^{4'} is hydroxyl, R⁴ is hydrogen, R^{5'} is hydroxyl, and R⁵ is hydrogen, Z' is not N." Thus, the compound disclosed in Yoneda is not within the scope of Applicants' claim 33.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

C. Rejection based on Minakawa et al. (Heterocycles, 1996, Vol. 42, no. 1, pp. 149-154)

The Examiner rejects claims 26 and 29 under 35 U.S.C. § 102(b) as allegedly being anticipated by Minakawa et al. (Heterocycles, 1996, Vol. 42, no. 1, pp. 149-154) ("Minakawa"). Office Action at page 7. The Examiner asserts that compound 19 in Minakawa "is the compound of formula 2(D) and the compound 2(H), when Z is N, X is NH₂, Y is O, R⁴ and R⁵ are H, and R^{4'} and R^{5'} are OH." *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. § 2131. Here, Minakawa fails to teach or suggest each and every element of claims 26 and 29. Claim 26, as amended, includes a proviso that "for compounds of formula 2 (D), when X is OH or NH₂, Y is O, W is O, R^{4'} is hydroxyl, R⁴ is hydrogen, R^{5'} is hydroxyl, and R⁵ is hydrogen, Z is not N." (Emphasis added). Similarly, claim 29, as amended, includes a proviso that "for compounds of formula 2 (H), when X is OH or NH₂, Y is O, R^{4'} is hydroxyl, R⁴ is hydrogen, R^{5'} is hydroxyl, and R⁵ is hydrogen, Z is not N." (Emphasis added). Thus, it is clear that compound 19 in Minakawa is not within the scope of claims 26 and 29.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. REJECTIONS UNDER 35 U.S.C. § 103

A. Rejection over Sasaki et al. (Journal of Organic Chemistry, 1976, vol. 41, no. 7, pp. 1100-1104)

The Examiner rejects claims 21-22 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sasaki et al. (Journal of Organic Chemistry, 1976, vol. 41, no. 7, pp. 1100-1104) ("Sasaki"). Office Action at page 8. The Examiner asserts that "Sasaki et al. teach a nucleoside analog, Compound 4, which is homolog of the compound of the formula 1(V), i.e., they differ only by a CH₂ group." *Id.* The Examiner further asserts that "compounds that are structurally homologous to prior art compounds are prima facie obvious." *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

Several basic factual inquiries must be made in order to determine whether the claims of a patent application are obvious under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

383 U.S. at 17, 148 U.S.P.Q. at 467. The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*,

383 U.S. at 17-18, 148 U.S.P.Q. 467; *see also KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007). It is important to note that a prior art reference relied upon in a rejection "must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. § 2141.02(VI).

In the present case, the Examiner has not established a *prima facie* case of obviousness. In order to establish the initial burden of establishing a *prima facie* case of obviousness, the Examiner first must show that the prior art references teach or suggest all the claim limitations. *See In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Here, the Examiner has not met that burden because Sasaki fails to teach or suggest all of Applicant's claim limitations. Indeed, the Examiner admits this deficiency in Sasaki on page 8 of the Office Action stating that Sasaki teaches a compound that differs from a compound of formula 1 (V), "i.e., they differ only by a CH₂ group." (Emphasis added).

The key, moreover, "to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. § 2141(III). The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, citing *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). Applicants respectfully submit that such articulated reasoning is not present in the rejection of record at least because no rationale is set forth for why one of ordinary skill in the art would have modified compound 4 disclosed in Sasaki by substituting the hydrogen atom with a CH₂ group.

In support of his rejection the Examiner relies on *In re Hass*, 60 U.S.P.Q. 544 (C.C.P.A. 1944) and contends that "compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results." Office Action at page 8. In *In re Hass*, the court considered claims drawn to members of a homologous series that expressly excluded a prior art member of that series. 60 U.S.P.Q. 544. In the present case, we do not have such a relationship. Thus, *In re Hass*, and likewise *In re Henze*, the other case cited by the Examiner, are not relevant authority for determining the obviousness of claims 21 and 22.

Homology must be considered with all other relevant facts in determining the issue of obviousness. See M.P.E.P. § 2144.09(II). Homology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed "as a whole." See *id.*; see also *In re Langer*, 465 F.2d 896, 175 U.S.P.Q. 169 (C.C.P.A. 1972). Here, the Examiner's conclusion of obvious is based on the assumption that it would have been obvious to modify Compound 4 in Sasaki by adding a methyl group. Courts, however, have specifically rejected the legal conclusions of obviousness based on general statements that "the modification of a compound by the addition of one or more methyl groups is well known and thus obvious." *In re Wagner*, 371 F.2d 877, 152 U.S.P.Q. 522, 558 (C.C.P.A. 1967) (The claims recited benzimidazole derivatives substituted with at least one alkyl group at two specific positions and the prior art taught benzimidazole derivatives having no substitutions at these positions). As in *In re Wagner*, the Examiner has merely provided such general statements without pointing to any additional facts demonstrating that it

would have been obvious to one of ordinary skill in the art to make the substitution at the particular location at which Applicants have placed the substituent. Accordingly, Applicants submit that the rejection of claims 21 and 22 under 35 U.S.C. § 103(a) over Sasaki is in error and should be withdrawn.

In addition with respect to claim 22, the Examiner asserts that hydrochloric acid, which is used by Sasaki, is a pharmaceutically acceptable carrier. See Office Action at page 9. However, as Applicants previously pointed out, a pharmaceutically acceptable carrier must be capable of being administered to a host without harming the host. One of skill in the art would not administer a compound in hydrochloric acid to a host since it is well-known in the art that hydrochloric acid is potentially harmful to a host. For this additional reason, claim 22 would not have been obvious over Sasaki.

For at least the reasons discussed above, Applicants submit that the Examiner's rejection is in error and respectfully request withdrawal of this rejection.

B. Rejection over Sasaki in view of Gilbert et al. (Antimicrobial Agents and Chemotherapy, 1986, Vol. 30, No. 2, pp. 201-205)

Claims 23-24 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sasaki in view of Gilbert et al. (Antimicrobial Agents and Chemotherapy, 1986, Vol. 30, No. 2, pp. 201-205) ("Gilbert"). Office Action at page 9.

Claims 23 and 24 depend from claim 21. As discussed in Section III.A. above, Sasaki fails to disclose or suggest a composition comprising an effective amount of a compound of claim 21. Gilbert does not remedy this deficiency in Sasaki. Accordingly, Applicants submit that the rejection is improper and should be withdrawn.

IV. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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